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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,544	05/30/2001	R. Rox Anderson	910000-2001	1057
21874	7590	03/13/2006	EXAMINER	
EDWARDS & ANGELL, LLP			FARAH, AHMED M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

3735

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,544

Applicant(s)

ANDERSON ET AL.

Examiner

Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-23 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,6-10 and 12-19 is/are allowed.
- 6) ☒ Claim(s) 11,20-23,25-39 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the heating" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 39, 46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebern et al. "*Laser treatment of nevus flammeus (portwine stain) with spectroscopic feedback: the smart scalpel*," Proc. SPIE, vol. 3519, pp. 32-42, 1999.

Sebern et al. disclose apparatus and method of use to non-invasively identify and locate one or more subsurface tissue targets for laser treatment, the apparatus comprising: means for directing light at a tissue site; means for detecting a reflected

light; means for locating untreated subsurface tissue structure; and means for treating the target/desired tissue with laser beams as presently claimed (see Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-23, 25-39 and 46-50 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan et al. U. S. Patent No. 5,860,967 in view of Sinofsky U.S. Patent No. 5,071,417.

As to claims 20, 34, 35, 39, 46, and 48-50, Zavislan et al. disclose apparatus and method for non-invasively identifying and locating one or more subsurface targets based on predetermined conditions for selective laser treatment at a tissue surface, the apparatus comprising:

means for directing one of polarized and an unpolarized light having a predetermined wavelength at a tissue site (see Fig. 3);

means (CCD camera) for detecting one or more reflections of light using a multi-dimensional photo-sensor;

means for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see the abstract); and

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means (laser **20** and laser controller **24**) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 21 and 22, the determined characteristics include at least the size, shape, and photometric properties of the tissue at one or more subsurface targets.

As to claims 23-25, the controller means **24** pulses the laser beam and adjusts one or more parameters of the laser beam, such as spot size, pulse width, etc.

As to claims 26 and 27, the spot size of the laser beam is adjusted through the movement of focusing lens **42**.

As to claim 31, the feedback system is controlled by both the operator and computer system. Hence, it is a semi-automatic feedback control.

As to claim 32, the spot size used by Zavislan et al. is about 500 microns, which is less than 3 mm (see col. 4, lines 58-64).

As to claims 37 and 47, the system of Zavislan et al. further comprises a means for determining a polarization of one or more reflections, wherein the location and one or more characteristics of the subsurface target are determined based upon said polarizations as presently claimed (see col. 6, lines 1-11).

As to claim 38, the treatment laser beam heats the target tissue thereby modifying the characteristics of said tissue.

However, although the controller system of Zavislan et al. is capable to provide a real time adjustment of the treatment laser in accordance with a desired treatment, they

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do not particularly teach a closed loop system as recited. Nevertheless, the use of a feedback control system for non-invasive treatment of a patient is known in the art.

Sinofsky discloses a system and method of use for fusion of biological tissue, the system comprising:

means for directing a laser light (one of polarized and an unpolarized light) having a predetermined wavelength at a tissue site, said laser light heating the tissues at the target site;

means (reflectance monitor **18**) for detecting one or more reflections of light using a multi-dimensional photo-sensor;

means (display **24**) for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see Fig. 1); and

means (controller **16**, laser **12**, and tuner **26**) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 28 and 30, the reflectance monitor performs real time monitoring/tracking of the target tissue; and the laser delivery unit **20** directs the treatment laser in response to the detected signals. Therefore, in the system of Sinofsky, the directing, detecting, and the determining functions are performed in real time (i.e., rapid feedback for tracking rapid relative movement between the treatment system and target site).

As to claim 29, the rapid feedback has a bandwidth of more than 0.5 HZ. This is due to the fact that for the tracking to be in real time, the response time of the system (the time between the detection of the reflected system, analyzing the data, and determining the tissue parameter, such as its location) must be much less than 2 seconds. Therefore, even if the response time is about 1 second, the rapid feedback has a bandwidth of 1 HZ, which is more than the recited 0.5 Hz.

As to claim 33, Sinofsky teaches that his invention is practiced with a wide variety of laser sources, including continuous wave ("c.w.") or pulsed modes (see col. 4, line 68 to col. 5, line 2).

As to claim 36, the feedback control is one of a closed-loop and quasi-closed-loop feedback control as presently claimed.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to use a closed loop system to adjust, in real time, at least one or more parameters of the treatment energy in accordance with the desired treatment so as to reduce treatment time. The use of a feedback control, closed-loop system would obviate the need of manual errors and operator delays.

Allowable Subject Matter

Claims 1-4, 6-10 and 12-19 are allowed.

Claim 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed December 8, 2005, have been fully considered but they are not persuasive. The applicants argue that neither Zavislan (US Pat. '967) nor Sinofsky (US Pat. '417), disclose, teach or suggest a system or step of automatically determining the location and characteristics of the subsurface targets as recited in the amended claims 20, 39, 46, 48 and 49.

In response to this argument, the court held that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result. In re Venner, 120 USPQ 192.

Conclusion

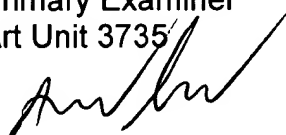
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on (571) 272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah
Primary Examiner
Art Unit 3735



February 20, 2006.